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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Foley & Lardner
3000 K Street NW Suite 500
Washington, DC 20007-5109

EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,834

Applicant(s)

MSIKA, PHILIPPE

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claims 1-15 are pending.

Specification

This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of stretchmarks, does not reasonably provide enablement for preventing of stretchmarks. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence

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or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The disclosure of the present invention is directed to a method of treating or preventing stretchmarks as set forth in independent claim 1. A skilled practitioner in the art using the teachings of Moy (5,759,555) and Rapaport et al. (5,444,091) would be motivated to reduce or eliminate stretchmarks. However, preventing stretch marks is inconsistent with what is known in the art since (1) reduction of stretch marks indicates that stretch marks are decreased, but not prevented; and (2) elimination of stretch marks indicates that symptoms of stretch marks may occur. Furthermore, prevention of stretch marks indicates that the subject never experiences any characteristics associated with stretch marks. Hence, the amount of guidance present in the specification, the absence of data indicating that the symptoms of stretch marks do not occur when the instant composition is administered, and the state of the prior art indicating that the treatment is possible, all indicate that treatment, not prevention of hair loss is possible.

The amount of guidance necessary to perform Applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous conditions and amounts of the instant composition to determine what composition prevents stretch marks. Hence, the amount of guidance present in the specification fails to present the necessary instruction such that one can readily determine the appropriate composition of claims 1-15.

Note: The Examiner reviewed Applicant's specification, but noted that the data does not indicate prevention of stretch marks.

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Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 1-15 are vague and indefinite, as it is not clear how the composition can prevent stretch marks? Does that mean that pregnant women who gain large amounts of weight will not obtain stretch marks using this composition?

(ii) The phrase "skin liable to form" in claims 1 and 2 (line 3; lines 3-4) is vague and indefinite, as it is not clear what skin is liable to form stretchmarks. The specification does not define this skin and one of ordinary skill in the art would not be appraised of it.

(iii) The phrase "soya peptides and tripeptides" in claims 1 and 2 (lines 6-7; line 7) is vague and indefinite, as it is confusing? Does this refer to soya peptides and soya tripeptides or does it refer to something else?

(iv) The phrase "fermented soya peptides and tripeptides" in claim 2 (line 7) is vague and indefinite, as it is not clear what the difference is between soya peptides and tripeptides, and fermented soya peptides and tripeptides?

(v) Claims 3, 8, and 13 contain the trademarks/trade names Phytokine and Kollaren-CPP. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or

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describe the goods associated with the trademark or trade name. In the present case, the trademarks/trade names are used to identify/describe a soya peptide and a tripeptide and, accordingly, the identification/description is indefinite.

(vi) The phrase "a-hydroxy acid" in claims 5 and 7 (lines 2) is vague and indefinite, as it is not clear what "a-hydroxy acid" is. Is it an alpha hydroxy acid?

(vii) Claims 8 and 13 are vague and indefinite. Are both the soya peptide and the tripeptide in combination with the lactic acid or is only the tripeptide in combination with the lactic acid.

(viii) Claim 15 provides for the use of a composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (5,614,215) in view of Shaffer et al. (5,760,079) in further view of Moy (5,759,555), Blanc-Ferras et al. (6,114,336), and De La Charriere et al. (2001/0014342).

Ribier et al. teach cosmetic compositions for the treatment of the surface and deep layers of the skin. Soya peptide extracts are disclosed for use in the composition as anti aging agents and moisturizers. The reference fails to teach chelating agents, substance P and neuropeptide Y inhibitors, See Col. 2, line 35-Col. 9, line 64.

Shaffer et al. teach a method of applying alpha hydroxy acids for treating striae distensae (stretchmarks). Citric acid, pyruvic acid, lactic acid, and glycolic acid are disclosed as alpha hydroxy acids. Chelating agents, botanical extracts and other ingredients are added to the composition. See Col. 3, line 20-Col. 8, line 45.

Moy teach cosmetic formulations and methods for ameliorating skin keratoses and striae distensae (stretchmarks). The formulation is disclosed as comprising lipids from avocado seed or fruit, zinc and/or copper chelates, and a water phase. See Col. 3, line 16-Col. 8, line 60.

Blanc-Ferras et al. teach cosmetic compositions containing a neuropeptide Y receptor antagonist. The neuropeptide Y receptor antagonist compound is disclosed as an extract of cells or tissues of animal or plant origin or a product obtained by fermentation of a microorganism.

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When placed on the epidermis, the composition has the effect of imparting to the skin a healthy appearance and of firming and smoothing the skin. See abstract; Col. 24, line 63-Col. 28, line 45.

De La Charriere et al. teach the use of substance P antagonist in a cosmetic composition. The composition is disclosed as combating desquamation. See pg. 2 [0022]-pg. 4 [0093].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the composition of Ribier et al. with that of Shaffer et al. and obtain a method of treating stretchmarks with a composition comprising soya peptides, chelating agents, and botanical extracts because a) Ribier et al. and Shaffer et al. both teach cosmetic compositions for topical application on the skin, wherein the cosmetic compositions provide skin benefits; b) Shaffer et al. teach his compositions as containing botanical or animal extracts and Ribier et al. teach soy peptide as an extract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the combined references using the teachings of Moy and obtain a method of treating stretchmarks with a composition comprising soy peptides, zinc and/or copper amino acid chelates, and botanical extracts because a) the combined references and Moy both teach cosmetic compositions for treating skin keratoses and striae distensae; b) Shaffer et al. teach chelating compounds in composition and Moy teach zinc and copper amino acid chelates.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the combined references using the teachings of Blanc-Ferras et al. and De La Charriere et al. and obtain a composition comprising soya peptides,

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zinc and/or copper chelates, substance P and neuropeptide Y inhibitor because a) the combined references and Blanc-Ferras and De La Charrieire et al. all teach cosmetic compositions for topical application to the skin to provide skin benefits; b) Shaffer et al. teach his composition as comprising animal and botanical extracts and De La Charrieire teach neuropeptide Y inhibitor as an extract of cells or tissues of animal or plant.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Prior Art


The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to the applicant's disclosure and shows the state of the art in its field but is not determined by the Examiner to read upon the invention currently being prosecuted in this application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


DAMERON L JONES
PRIMARY EXAMINER